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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,036	05/15/2001	Shinichi Kanno	31090.0015	2475

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04/19/2004

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EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

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DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,036

Applicant(s)

KANNO ET AL.

Examiner

Kristen L Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/8/04 (response).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-15 is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, and 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanakis et al. (5,433,735).

Regarding claim 1, Zanakis et al. shows a method of inducing angiogenesis in a muscle tissue comprising the steps of applying electrical voltage to one or more areas of the muscle tissue, wherein the electrical voltage does not induce contraction of the muscle cells and wherein angiogenesis is induced after application of the electrical voltage (Col. 3, lines 60-64, Col. 5, lines 52-65; Col. 9, lines 7-19, 56-62).

It is inherent that angiogenesis comprises an increase in capillary density since angiogenesis is defined in Stedman's Medical Dictionary as the development of new blood vessels.

With respect to claim 3, it is inherent that the muscle cells of a vessel wall musculature are smooth muscle cells.

Regarding claim 4, Zanakis et al. shows the muscles are skeletal muscles (Col 9, lines 20-24)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zanakis et al. Zanakis et al. discloses the claimed invention except for the electrical voltage being 0.1V at 50Hz. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the voltage and frequency as taught by Zanakis et al. with 0.1V at 50Hz, since applicant has not disclosed that this particular voltage and frequency provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any voltage and frequency such as the voltage and frequency taught by Zanakis et al. et al. for inducing angiogenesis without inducing contraction of the muscle cells.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zanakis et al. Zanakis et al. is as explained before. Zanakis et al. fails to specifically point out that the muscle cells are cardiac muscle cells but teaches that treatment of the damaged tissue can be anywhere in the body especially those tissues subject to the greatest chance of trauma (Col. 2, lines 19-24); Zanakis et al. also teaches that it is an object of the invention to promote blood perfusion in the damaged tissues (Col. 3, lines 19-24). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to include cardiac muscle cells in the method of Zanakis et al. since it is well known that cardiac muscle cells are subject to ischemia (trauma) when a patient

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suffers a heart attack, and the promotion of blood perfusion in the damaged cardiac muscle cells would be beneficial to offsetting the effects of ischemia.

Response to Arguments

6. Applicant's arguments filed 3/8/04 have been fully considered but they are not persuasive. Angiogenesis is defined as the development of new blood vessels. New blood vessels developed in a unit volume of tissue would increase the number of capillaries in the unit volume of tissue, thus increasing the capillary density. Capillaries are found near every cell in the body in order to supply oxygen and nutrients to those cells. The growth of new blood vessels would be necessary in the healing process in order to supply oxygen and nutrients to the newly generated cells.

Allowable Subject Matter

7. Claims 5-15 are allowed. The prior art of record fails to teach or suggest a method of increasing Vascular Endothelial Growth Factor (VEGF) or VEGF mRNA in a muscle cell by the application of electrical voltage to the muscle cell and where the electrical voltage does not cause contraction of the muscle cell.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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